510(k) Summary K014234

Submitter:	Continuum Electro-Optics, Inc. 3150 Central expressway Santa Clara, CA 95051
Contact:	Ronald Kohlhardt
Date Summary Prepared:	December 19, 2001
Device Trade Name:	Medlite C6 Q-Switched Nd:YAG Laser
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX
Equivalent Device(s):	Medlite™ IV Q-Switched Nd:YAG Laser Medlite™ Q-Switched Nd:YAG Laser Medlite™ C3 Q-Switched Nd:YAG Laser
Intended Use:	• Tattoo Removal • Treatment of Vascular Lesions • Treatment of Pigmented Lesions • Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology • Removal or lightening of unwanted hair with or without adjuvant preparation
Comparison:	The Medlite C6 Q-Switched Nd:YAG Laser bases its design/construction from the integration of primary subsystems extracted from legally marketed predicate Continuum products. The new device performs and is specified within all product parameters of the predicate devices.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Additional Information:	None

JAN 1 7 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 7 2002

Continuum Electro-Optics, Inc.
Ronald Kohlhardt
Director, Regulatory Compliance and Quality Assurance
3150 Central Expressway
Santa Clara, California 95051-0801

Re: K014234
Trade Name: Medlite C6 Q-Switched Nd: YAG Laser
Regulation Number: 878.4810
Regulation Name: Laser Surgical Instrument
Regulatory Class: II
Product Code: GEX
Dated: December 19, 2001
Received: December 26, 2001

Dear Mr. Kohlhardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014234

Device Name: Medlite C6 Q-Switched Nd:YAG Laser.

Indications for Use:

Tattoo Removal
- dark ink: blue and black
- light ink: red
- light ink: sky blue
- light ink: green

Treatment of Vascular Lesions
- port wine birthmarks
- telangiectasias
- spider angioma
- cherry angioma
- spider nevi

Treatment of Pigmented Lesions
- cafe-au-lait birthmarks
- solar lentiginos
- senile lentiginos
- becker's nevi
- freckles
- nevus spilus
- nevus of ota

Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology

Removal or lightening of unwanted hair with or without adjuvant preparation

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014234

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)